

10/584810  
IAP11 Rec'd PCT/PTO 28 JUN 2006

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Donald J. Graham et al.

Serial No. to be assigned

Filed:

For: HCV RNA-DEPENDENT RNA POLYMERASE

Art Unit: \_\_\_\_\_

Examiner: \_\_\_\_\_

Commissioner for Patents  
P.O. Box 1450  
Alexandria, Virginia 22313-1450INFORMATION DISCLOSURE STATEMENT  
UNDER 37 CFR 1.97

Sir:

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3. Applicants respectfully request that the Examiner initial the attached form after reviewing the pertinence of each reference.

4. Pursuant to 37 C.F.R. 1.98 (a)(2)(ii), copies of each cited U.S. patent and each U.S. patent application publication are not enclosed herewith.

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By \_\_\_\_\_ Date \_\_\_\_\_

## INFORMATION DISCLOSURE STATEMENT

5. Pursuant to 37 C.F.R. 1.98(d), copies of references listed on the attached form that were submitted to or cited by the Office in a related application upon which the instant application relies for an earlier filing date under 35 U.S.C. 120 are not enclosed. Related application(s) in which references were submitted to or cited by the Office are as follows:

RELATED APPLICATION		
U. S. SERIAL NUMBER	FILING DATE	MERCK CASE

If this is inconvenient, additional copies will be submitted upon request.

6. In accordance with 37 C.F.R. 1.97, (check one)

- ☒ the attached information is filed within three months of the filing date of the captioned case.
- ☐ the attached information is filed more than three months after the filing date but prior to the mailing of a first Office Action on the merits.
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- ☐ the attached information is being filed more than three months after the filing date and after the mailing of a first Office Action on the merits, but before the mailing date of a Final Action, Notice of Allowance, or an action that otherwise closes prosecution in the application. The enclosed authorization is therefore given to charge Deposit Account No. 13-2755 for the fee required under 37 C.F.R. 1.17(p).
- ☐ each item of information contained in this Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Statement.
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- ☐ no item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, was known to any individual designated under 37 C.F.R. 1.56(c) more than three months prior to the filing of this Statement.

Respectfully submitted,



By: Sheldon O. Heber

Attorney \_\_\_\_\_ For Applicant(s)

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Date: 6-28-06



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Substitute for form 1449B/PTO <b>INFORMATION DISCLOSURE</b>  <b>STATEMENT BY APPLICANT</b>  <i>(use as many sheets as necessary)</i>				Application Number	
				Filing Date	
				First Named Inventor	
				Group Art Unit	
				Examiner Name	
Sheet	2	of	4	Attorney Docket Number	
				21471P	

NON PATENT LITERATURE DOCUMENTS		
Examiner Initials*	Cite No.	Include name of the author, title, date, page(s), volume-issue number(s) and place of publication.
	A	NCBI, AF177036 Hepatitis C virus... [gi:6010579] Oct 5, 1999
	B	NCBI, P26661 Genome polyprotein [gi: 130468] June 15, 20002
	C	NCBI, D17763 Hepatitis C Virus [gi: 514395] February 4, 1999
	D	Bartenschlager et al. 'Nonstructural Protein 3 of the Hepatitis C Virus... at the NS3/4 and NS4/5 Junctions', Journal of Virology, Vol 67, No. 7, pp 3835-3844 July 1993
	E	Beaulieu, et al. 'Non-Nucleoside Inhibitors of the Hepatitis C Virus NS5B...Benzimidazole Derivatives', Bioorganic & Medicinal Chemistry Letters, Vol. 14 pp 119-124 (2004)
	F	Behrens et al. 'Identification and Properties of the RNA-Dependent RNA Polymerase of Hepatitis C Virus, EMBO, Vol 15, No. 1, pp 12-22 (1996)
	G	Carroll, et al.. 'Inhibition of Hepatitis C Virus RNA Replication by 2'-Modified Nucleoside Analogs', Journal of Biological Chemistry, Vol, 278, No. 14, Issue of April 4, pp 11979-11984 (2003)
	H	Choo et al., 'Isolation of a cDNA Clone Derived from a Blood-Borne Non-A, Non-B Viral Hepatitis Genome', Science, Vol. 244pp 359-361, (April 1989)
	I	De Francesco et al. 'RNA-Dependent RNA Polymerase of Hepatitis C Virus', Methods in Enzymology, Vol. 275, pp 58-67,
	J	Farci et al. 'Clinical Significance of Hepatitis C Virus Genotypes and Quasispecies', Seminars in Liver Disease, Vol. 20, No. 1, pp 103-125 (2000)
	K	Ferrari, et al. 'Characterization of Soluble Hepatitis C Virus RNA-Dependent RNA Polymerase Expressed in Escherichia coli', Journal of Virology, Vol. 73, No. 2, pp 1649-1654 (Feb 1999)
	L	Grakoui, et al. 'A Second Hepatitis C Virus-Encoded Proteinase', Proc. Natl. Sci. USA, Vol 90, pp 10583-10587 (November 1993)
	M	Huikata, et al. 'Proteolytic Processing and Membrane Association of Putative Nonstructural Proteins of Hepatitis C Virus, Vol. 90, pp 10773-10777 (November 1993)
	N	Kolykhalov et al. 'Transmission of Hepatitis C by Intrahepatic Inoculation with Transcribed RNA', Science, Vol. 277 pp 570-574, (July 25, 1997)
	O	Kuo et al., 'An Assay for Cirulating Antibodies to a Major Etiologic Virus of Human Non-A, Non-B Hepatitis', Science, Vol 244, pp 362-364 (1989)

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\*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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			Filing Date		
			First Named Inventor		Donald J. Graham
			Group Art Unit		
			Examiner Name		
Sheet	3	of	4	Attorney Docket Number	21471P

NON PATENT LITERATURE DOCUMENTS		
Examiner Initials*	Cite No.	Include name of the author, title, date, page(s), volume-issue number(s) and place of publication.
	P	Leveque et al. 'Identification of a C-Terminal Regulatory Motif in Hepatitis C Virus RNA-Dependent RNA Polymerase: Structural and Biochemical Analysis', Journal of Virology, Vol 77, No. 16, pp 9020-9028 (August 2003)
	Q	Lohmann et al. 'Biochemical and Kinetic Analyses of NSB RNA-Dependent RNA Polymerase of the Hepatitis C Virus', Virology, Vol. 249, pp 108-118 (1998)
	R	Luo et al. 'De Novo Initiation of RNA Synthesis by the RNA-Dependent RNA Polymerase (NS5B) of Hepatitis C Virus', Journal of Virology, Vol. 74, No. 2, pp 851-863 (January 2000)
	S	Migliaccio et al. 'Characterization of Resistance to Non-Obligate Chain-Terminating Ribonucleoside Analogs that Inhibit Hepatitis C Virus Replication in Vitro', Journal of Biological Chemistry, Vol. 278, No. 49, Issue of December 5, pp 49164-49170 (2003)
	T	Mizushima et al. 'Analysis of N-Terminal Processing of Hepatitis C Virus Nonstructural Protein 2', Journal of Virology, Vol. 68, No. 4 pp 2731-2734 (April 1994)
	U	Oh, et al. 'A Recombinant Hepatitis C Virus RNA-Dependent RNA Polymerase Capable of Copying the Full-Length Viral RNA', Journal of Virology, Vol. 73, No. 9, pp 7694-7702 (Sept. 1999)
	V	Okamoto et al. 'Full-length Sequence of a Hepatitis C Virus Genome Having Poor Homology ... of Four Distinct Genotypes', Virology, Vol. 188, pp 331-341 (1992)
	W	Regenmortel et al. Seventh Report of the International Committee on Taxonomy of Viruses; Virus Taxonomy - Classification and Nomenclature of Viruses, Academic Press, p 876 (2000)
	X	Sakamoto et al. 'Entire Nucleotide Sequence and Characterization of a Hepatitis C Virus of Genotype V/3a', Journal of General Virology, Vol. 75, Pt 7, pp 1761-1768 (1994)
	Y	Shim et al. 'Canonical 3'-deoxyribonucleotides as a Chain Terminator for HCV NS5B RNA-dependent RNA Polymerase', Antiviral Research, Vol. 58, pp 243-251 (2003)
	Z	Takamizawa et al. 'Structure and Organization of the Hepatitis C Virus Genome Isolated from Human Carriers', Journal of Virology, Vol. 65, No. 3, pp. 1105-1113 (March 1991)
	AA	Tomei, et al. 'NS3 Is a Serine Protease Required for Processing of Hepatitis C Virus Polyprotein', Journal of Virology, Vol. 67, No. 7, pp 4017-4026 (July 1993)
	AB	Walker et al. 'HCV RNA-dependent RNA Polymerase as a Target for Antiviral Development', Current Opinion in Pharmacology, Vol. 2, pp 1-7 (2002)
	AC	Yamashita et al. 'RNA-dependent RNA Polymerase Activity of the Soluble Recombinant ...C-terminal Region', Journal of Biological Chemistry, Vol. 273, No. 25, Issue of June 19, pp 15479-15486 (1998)
	AD	Yanagi, et al. 'Transcripts from a Single Full-length cDNA Clone of Hepatitis C Virus ... the Liver of a Chimpanzee', Proc. Natl. Acad. Sci. USA, Vol. 94, pp 8738-8743 (August 1997)

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